DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Alan H. Kaplan, Esq.
Richard S. Morey, Esq.
Kleinfeld, Kaplan and Becker
1140 Nineteenth Street, N.W.
Washington, D.C. 20036-6601

Re: Docket No. 99P-0792/CP1

Dear Mr. Kaplan and Mr. Morey:

This responds to your citizen petition, dated March 29, 1999, requesting that the Food and Drug Administration (FDA) modify its policy of determining that an abbreviated new drug application (ANDA) for each strength of a drug product is eligible for 180-day generic drug exclusivity under section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355(j)(5)(B)(iv)). Your petition is granted to the limited extent that current Agency practice achieves the policy goal stated in your petition.

You ask that the modification apply when the first eligible ANDA applicant is sued for patent infringement by the patent owner or new drug application (NDA) holder and a final court decision is issued holding that all patents listed for the reference drug are invalid or unenforceable. Under those circumstances, you request that the first applicant's 180-day exclusivity period apply to all strengths of a reference listed drug containing the same active ingredient(s), indications, and directions for use, and for which the same patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the *Orange Book* (Petition at 1-2). Under the proposed modification, the Agency could approve all otherwise eligible ANDAs upon expiration of the first applicant's 180-day exclusivity because no applicant would be eligible for exclusivity for any strength of the reference listed drug after the first applicant received exclusivity for its strength.

You state that implementation of your request "would permit earlier eligibility for approval and market availability under 'subsequent' ANDAs" (Petition at 3). Under current Agency practice, this goal is achieved.

When an applicant submits a paragraph IV certification (see section 505(j)(2)(A)(vii) of the Act) stating that the patent is invalid or unenforceable, and a court holds that the patent is invalid or unenforceable, the Agency will remove that patent from the *Orange Book* after the expiration of the applicable 180-day exclusivity period. After the patent is removed from the *Orange Book*, ANDA applicants are no longer required to make a paragraph IV certification with respect to the removed patent and all ANDA applicants for the listed drug must amend their patent certifications accordingly. (21 CFR 314.94(a)(12)(i) and 314.94(a)(12)(viii)(B); see also 59 FR 50338 at 50348, October 3, 1994). At that time, the invalid or unenforceable patent no longer presents a

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barrier to final approval of any otherwise eligible ANDAs for all strengths of the listed drug. This practice allows for the "earlier potential for all dosage strengths of the reference drug to be made available" as requested in your petition (Petition at 7).

The Agency recently published a proposed rule addressing 180-day generic drug exclusivity. (See 64 FR 42873, August 6, 1999.) That rule addresses the Agency's proposed treatment of exclusivity for different strengths of a drug product (64 FR at 42881). If all the concerns or situations you intended to raise in your petition are not satisfactorily addressed, or if you have further comments on any issues pertaining to 180-day generic drug exclusivity, the Agency encourages you to submit them to the Dockets Management Branch as described in the proposed rule. (See 64 FR 42873.)

Your petition is granted to the limited extent that current Agency practice achieves the policy goal stated in your petition.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research